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| EXAMINER | |
|---|---|
| KELLY, ROBERT M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | |

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/608,997 | PROCKOP ET AL. | |
| | Examiner | Art Unit | |
| | Robert M. Kelly | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,9-15,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-15,17 and 18* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendments and arguments of 6/19/06 are entered.

Claims 1 and 17 are amended.

Claims 8 and 16 are cancelled.

Claims 1-7, 9-15, and 17-18 are pending.

### *Election/Restrictions*

Claims 9-15 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/25/05.

Hence, Claims 1-7 and 17-18 are presently considered.

This application contains claims 9-15, drawn to an invention nonelected with traverse in the response to restriction requirement of 3/25/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Claim Status, Cancelled Claims*

In light of Applicant's cancellation of claims 8 and 16, all rejections and/or objections to such claims are rendered moot, and thus are withdrawn.

### *Claim Objections*

In light of the amendment to Claim 17, the prior objection to such claim is withdrawn.

Claim 17 is newly objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for one of the embodiments of the markush group. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 15, in one of the embodiments encompassed by the Markush group "culturing cells in vitro, and pre-differentiating said cells", if the embodiment of pre-differentiating said cells is chosen, it would fail to further limit the base claim, because claim 1 requires such pre-differentiation.

### *Drawings*

In light of Applicant's cancellation of figure 6, the objection to the drawings are rendered moot, and thus, are withdrawn.

The drawings are objected to not containing a figure 6. Specifically, Applicant has cancelled figure 6, but the drawings contain a figure 6. The drawings are required to be numbered consecutively.

### *Specification*

The specification is objected to for not containing a brief description of Figure 6, while it contains a brief description of Figure 7. To wit, the drawings must be consecutive numbering.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the isolated stromal cells are administered to the CNS of the patient, by administration of the pre-differentiated isolated stromal cells. It is unclear how isolated stromal cells are administered by administration of the pre-differentiated isolated stromal cells.

Claim 1 is also unclear as to the metes and bounds of the pre-differentiation step. To wit, such step can be interpreted to be a first differentiation step required prior to the differentiation step after administration to the patient. As such, there exists no structural and/or functional requirements such that the Artisan could understand what is required to obtain such pre-differentiated cells.

Claim 1 also recites "a method of directing the differentiation of an isolated stromal cell into an astrocyte", and, "pre-differentiating the isolated stromal cells by co-culturing said stromal cells in the presence of astrocytes". However, subsequent steps require administration of the cells to a human patient suffering from a disease, disorder, or condition. From the specification, such patient administration appears to be more consistent with therapy, but not with differentiation of cells. Moreover, given that "directing the differentiation" is specifically defined in the specification to be limited to *in vitro*, it appears that such step of administration is

more consistent with therapy than with directing differentiation. Therefore, the metes and bounds of this claim are unclear.

Claim 1 recites the limitation "the brain" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 2-7 and 17-18 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in the base claim.

### *Claim Rejections - 35 USC § 112*

Claims 1-7 and 17-18 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record and the reasons given below. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 again contains limitation to differentiating cells by co-culturing *in vivo*. As was noted in the Official Action of 6/3/06, pp. 5-6, such is new matter. It is noted that Examiner previously withdrew this rejection, but is now reapplied due to the amendments. To wit, the preamble states "A method of directing the differentiation of an isolated stromal cell into an astrocyte in a human patient". As such, it is clear that such the step of "pre-differentiating" takes place *in vivo*. However, the Artisan would find that the specification, as previously noted, indicates that such co-culturing must take place *in vitro*. Hence, these claims again comprise new matter.

***Claim Rejections - 35 USC § 112 – new matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 17-18 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, and hence, Claims 2-7 and 17-18, comprise new matter for the step of pre-differentiating. Specifically, it appears that Applicant is attempting to claim a pre-differentiation step requiring co-culturing, wherein differentiation subsequently takes place in the human patient by administration of the pre-differentiated cells. Applicant relies, broadly, on the disclosure of Examples 7-8 (Response of 6/19/06, p. 7, paragraph 2). However, a review of the specification and examples provided only support for a specific coculturing with astrocytes, and such is not to "pre-differentiate" but to label the cells for fluorescence labeling of the nuclei of the cells (p. 49, paragraph 1). Moreover, such is limited to rats, in an example, and as such, fails to provide support for even this embodiment, in humans, as is required by the claim. Moreover no other support, either implicit or explicit was found by the Examiner in a cursory review of the specificiation. Applicant is reminded it is the burden of Applicant to provide proper support for claim amendments, and it is not Office's duty to find such support. Hence, these claims are drawn to new matter.

***Claim Rejections - 35 USC § 112 - Enablement***

Claims 1-8 and 16-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

***Response to Argument - Enablement***

Applicant's arguments of 6/19/06 have been fully considered but are not found persuasive.

Applicant argues that the experimentation required to practice the invention is not undue, but routine (pp. 8-9, paragraph bridging).

Such is not persuasive. Experimentation is undue because it is required to find any and all working embodiments encompassed by Applicant's claims. Moreover, the Examiner has provided reasons to doubt the efficacy of any and all embodiments (e.g., Official Action of 6/3/05, pp. 6-20), and as such the Artisan would have to experiment to find the conditions to effect any embodiment. Therefore, such experimentation would amount to inventing Applicant's invention for Applicant, and hence, it is undue experimentation.

Applicant argues that they have demonstrated such techniques, and therefore, the claims are enabled, specifically in EXAMPLES 7-8, and therefore, the claims are enabled (p. 9, paragraph 2).

Such is not persuasive. As has been stated, Applicant may have a preamble to directing differentiation, but the claimed steps, and teachings of the specification, indicate to the Artisan

that Applicant is actually claiming treatment (e.g., Official Action of 6/3/05, p. 8, last paragraph). Moreover, it is clear that is not reasonably predictable to treat any particular disease (Id., pp. 6-20). Lastly, Applicant's cited support is only under conditions of rats, and for labeled cell administration to rats, not for treating humans, and hence, consistent with the rejection under new matter (ABOVE), the Artisan would still find these claims to be directed to therapy.

Applicant argues that by amending the claims to encompass administration by injection, the claims are now enabled for the methods of administration (p. 9, last paragraph).

Such is not persuasive. Injection may be performed anywhere, to any tissue, including into the blood. As such, the claims remain rejected on such basis.

Applicant argues that clinical trials could be performed to determine the amount of cells to administer, and that routine dosage determination is routine (p. 10, paragraph 1).

Such is not persuasive. The fact remains that such experimentation is undue, amounting to inventing Applicant's invention for Applicant (See Arguments above and in the previous actions).

***Conclusion***

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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